DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region

95150d

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6004

December 7, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Robert Unanue, President
Goya Foods, Inc.
100 Seaview Dr.
Secaucus, New Jersey 07096

FILE NO.: 05-NWJ-05

Dear Mr. Unanue:

On June 25, 2004, an investigator from the New Jersey District Office of the Food and Drug Administration (FDA) collected a sample of Goya Fine Yellow Enriched Corn Meal (1 lb. 8 oz), lot # [redacted] manufactured by your firm. The sample was collected for nutrient content analysis to determine compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations in Title 21, *Code of Federal Regulations*. You can find the Act and regulations on FDA's web site at www.fda.gov.

Our analysis found your product to be adulterated within the meaning of section 402(b)(1) of the Act in that a valuable component, iron, has been in part omitted. Your product is also misbranded within the meaning of section 403(a)(1) of the Act because the labeling is false or misleading in that the amount of iron is not at least equal to the value for that nutrient declared on the label (21 CFR 101.9(g)(4)(i)). Your label declares that the product provides 17% of the Daily Value (DV) of iron per serving; however, our analysis found the iron content to be 8.5% (original analysis) and 7.49% (check analysis) of the value declared in the nutrition information on the label.

Your product is also misbranded within the meaning of section 403(g) of the Act in that it purports to be a food for which a definition and standard of identity has been prescribed by regulations, but it does not conform to such definition and standard. For example, according to 21 CFR 137.260 Enriched corn meals, such products must contain not less than 13mg and not more than 26mg of iron in each pound. According to our analysis, your product contains 3.58 mg/lb (original analysis) and 3.15 mg/lb (check

analysis) of iron. Furthermore, the information provided in the Nutrition Facts panel declares the amount of iron to be 17% DV per 33g serving; this calculates to be about 42 mg/lb of iron. Neither the figures from our lab analysis nor the amount declared in your Nutrition Facts panel complies with the iron requirements for enriched corn meals [21 CFR 137.260(a)(1)].

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure. This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling and nutrient analysis. You must ensure all products distributed by your firm comply with the Act and its implementing regulations.

In reviewing your label, we also noted that your Nutrition Facts panel fails to declare the amount of riboflavin in your product. Riboflavin is a nutrient that has minimum and maximum levels in the standard of identity for enriched corn meal, and in accordance with 21 CFR 101.9(c)(8)(ii), the nutrition information shall include the listing of riboflavin when it is added as a nutrient supplement. Furthermore, the values of several nutrients being declared in your Nutrition Facts panel (i.e., calories, sodium, vitamin A, iron, niacin and folate) do not comply with the rounding requirements as specified in 21 CFR 101.9(c).

You should notify this office in writing within 15 working days of receipt of this letter of any corrective actions, including an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay. Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director
New Jersey District Office